

Application No.: 10/766,106

Docket No.: PRJ-006CN

PENDING CLAIMS

1. **(Previously Presented)** A pharmaceutical formulation for controlled release of an interferon, the formulation comprising a biodegradable polymer in combination with a conjugate of an interferon and a hydrophilic polymer, wherein the hydrophilic polymer is linked to the interferon predominantly at a single site on the interferon.
2. **(Original)** The pharmaceutical formulation of claim 1, wherein the interferon is selected from the group consisting of alpha-interferon, beta-interferon, and gamma-interferon.
3. **(Original)** The pharmaceutical formulation of claim 1, wherein the interferon and the hydrophilic polymer are covalently conjugated.
4. **(Original)** The pharmaceutical formulation of claim 1, wherein the biodegradable polymer is selected from the group consisting of polyhydroxy acids, polylactic acids, polyglycolic acids, and copolymers thereof.
5. **(Original)** The pharmaceutical formulation of claim 4, wherein the biodegradable polymer is selected from the group consisting of polyanhydrides, polyorthoesters, and polysaccharide polymers.
6. **(Original)** The pharmaceutical formulation of claim 1, wherein the hydrophilic polymer is selected from the group consisting of polyethylene glycol, polypropylene glycol, copolymers of polyethylene glycol and polypropylene glycol, and linear and branched derivatives of polyethylene glycol and polyethylene glycol/polypropylene glycol copolymers.
7. **(Original)** The formulation of claim 1, wherein the formulation is in a form suitable for administration orally.
8. **(Original)** The formulation of claim 1, wherein the formulation is in a form suitable for administration by inhalation or mucosal delivery.

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9. (Original) The formulation of claim 1, wherein the formulation is in a form suitable for administration by injection.

10. (Original) The formulation of claim 9, wherein the injection is subcutaneous or intramuscular.

11. (Original) The formulation of claim 1, wherein the biodegradable polymer comprises a copolymer of polylactic acid and polyglycolic acid and the hydrophilic polymer comprises polyethylene glycol.

12. (Original) A method for producing a pharmaceutical formulation for controlled release of an interferon, the method comprising:

dissolving (a) a biodegradable polymer and (b) a conjugate of an interferon and a hydrophilic polymer in a solvent to form a monophase, and

forming microparticles or nanoparticles comprising the biodegradable polymer encapsulating the conjugate.

13. (Original) The method of claim 12, wherein the interferon is selected from the group consisting of alpha-interferon, beta-interferon, and gamma-interferon.

14. (Original) A pharmaceutical formulation for controlled release of an interferon, the formulation comprising a biodegradable polymer in combination with a conjugate of an interferon and a hydrophilic polymer, wherein the biodegradable polymer comprises a derivatized biodegradable polymer containing hydrophilic and hydrophobic regions.

15. (Original) The formulation of claim 14, wherein the hydrophilic region comprises polyethylene glycol.

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16. (Original) The formulation of claim 14, wherein the hydrophobic region comprises a polymer selected from the group consisting of polyhydroxy acids, polylactic acids, polyglycolic acids, and copolymers thereof.
17. (Original) The formulation of claim 15, wherein the polyethylene glycol is linked to the interferon predominantly at a single site on the bioactive molecule.
18. (Original) The pharmaceutical formulation of claim 14, wherein the interferon is selected from the group consisting of alpha-interferon, beta-interferon, and gamma-interferon.
19. (Original) A pharmaceutical formulation for controlled release of a bioactive molecule, the formulation comprising a biodegradable polymer in combination with a conjugate of a bioactive molecule and a hydrophilic polymer, wherein the formulation is in the form of microparticles encapsulating the conjugate, the microparticles having a diameter predominantly between 20 and 100 um.
20. (Original) The pharmaceutical formulation of claim 19, wherein the bioactive molecule is a protein.
21. (Original) A pharmaceutical formulation for controlled release of a peptide, the formulation comprising a biodegradable polymer in combination with a conjugate of a peptide and a hydrophilic polymer, wherein the conjugate is predominantly a single species.
22. (Original) The pharmaceutical formulation of claim 21, wherein the peptide comprises biphalin, leu-enkephalin, or somatostatin.